Claims 8-18, which are all of the claims pending in this application, stand rejected under 35 U.S.C. §112, first paragraph.

In particular, with respect to claims 12 and 17, the Examiner has asserted that the application as originally filed does not provide support for the "alarm" feature recited in those claims. However, contrary to this assertion, there are several places in the originally filed application that independently provide sufficient descriptive support to convey to one skilled in that art that the inventors have made a therapy apparatus that includes an alarm.

The "Summary of the Invention" discloses that (first full paragraph on page 9; emphasis added):

> The apparatus monitors the therapy temperature and produces an audible signal when the cold or heat source is exhausted and the apparatus is no longer able to maintain the desired therapy temperature within certain preset tolerances.

Claim 1, as originally filed, recites that (page 20, lines 16-20; emphasis added):

> a means to warn the user whenever the apparatus lacks sufficient capacity to control the therapy temperature at a constant value, or according to a therapy temperature-time profile, within a preset temperature tolerance value.

And claim 7, as originally filed, further describes the "means to warn" recited above in claim 1 as including (emphasis added):

> two thermistors connected to microprocessor-based control electronics and associated operating program, one said thermistor mounted in each of two supply tubes supplying controlled temperature fluid to a bladder

> device, said control electronics and associated operating program monitoring the output of said thermistors and producing an audible signal from a sound-emitting device when the temperature detected by said thermistors indicates that the cooling/heating capacity in said reservoir is insufficient for maintenance of the closed-loop therapy temperature control within the preset temperature tolerance value.

Thus, the application as originally filed descriptively supports the "alarm" feature recited in claims 12 and 17. Such disclosure clearly conveys to those skilled in the art that the inventors have made a therapy apparatus that includes an "alarm." We therefore ask that this rejection be withdrawn.

Further with respect to the rejection of claims 8-18, the Examiner has indicated that:

> Neither the written description nor the drawings gives sufficient information on the operation of the pump/heat exchanger.

In Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991), the Federal Circuit has indicated that:

> The purpose of [the enablement] requirement is to assure that the inventor provides sufficient information about the claimed invention that a person of skill in the field of the invention can make and use it without undue experimentation, relying on the patent specification and the knowledge in the art.

Contrary to the Examiner's assertion, however, the specification provides sufficient information for a person skilled in the art to make and use the invention without undue experimentation.

As shown in Fig. 2, in one embodiment, the heat exchanger includes a pump 13, a priming valve 14, and an

air/water separator 15. Pump 13 delivers pressurized water to a thermal therapy pad via quick disconnect 11. Water from the therapy pad is returned to the thermal therapy apparatus through air/water separator 15 via quick disconnect 12. Valve 14 receives thermal reservoir water from a tube 17 and receives recirculated water from air/water separator 15. Valve 14 thus provides "a means of exchanging a measured portion of the recirculation water with water from the reservoir to maintain the circulation of water at the desired temperature" (page 8, lines 8-10). The output of valve 14 is coupled to pump 13 to complete the fluid loop formed by the heat exchanger and the therapy pad.

The cooperation of the heat exchanger with the other elements of the therapy apparatus is described, e.g., at page 17, lines 6-19:

> The reservoir 19, pump/heat exchanger 13, supply tubes 41 and 42, and bladder 60 form a fluid circuit in which fluid may flow in either direction. Net flow through the bladder 60 is achieved by creating a pressurized output flow via the pump/heat exchanger 13 with the spent water returning from the bladder 60 to the air/water separator and ultimately to the inlet side of the pump/heat exchanger 13. The pump/heat exchanger 13, under microprocessor control, continuously displaces a precise amount of recirculation water with water from the constant temperature reservoir to precisely maintain the temperature of the circulation water exiting the pump/heat exchanger 13. The displaced recirculation water is returned to the reservoir via the air/water separator 15 to maintain a constant volume in the circulation system.

This disclosure provides sufficient information for one skilled in the art to make and use the invention without undue

experimentation. With this information, one skilled in the art can certainly make and use a heat exchanger comprising a pump for providing pressurized fluid to the therapy pad, a valve (under microprocessor control) for displacing a precise amount of recirculation water with water from the constant temperature reservoir to precisely maintain the temperature of the circulation water, and an air/water separator for returning recirculation water to the reservoir to maintain a constant volume in the circulation system.

The Examiner has also indicated that:

> There is insufficient information on the computer program and how its function relates to the given apparatus.

But it is clear that the computer program controls the microprocessor (page 18, lines 9-13):

> The control electronics 7 incorporate sufficient non-volatile electronic memory to allow storage, recall and implementation of a plurality of preprogrammed or user-programmed therapy temperature-time profiles, in addition to the operating program of the apparatus.

It is also clear that the microprocessor controls the heat exchanger (page 11, lines 7-10):

> By using the real-time temperature information generated by the temperature sensing devices, the microprocessor controls the rate of reservoir/recirculation fluid mixing within the heat exchanger. This maintains the circulation water temperature, and thus the injury site bladder temperature.

Thus, the function of the computer program is to control the temperature of the circulation water. The computer program also controls the application of tactile stimulation at the desired

therapy temperature (page 11, lines 23-27; see also page 17, line 25 through page 18, line 7):

> The microprocessor-based control electronics and associated operating program operate the pump accordingly to provide maximum flow or circulation fluid and impose periodic pressure variations on the bladder such that the desired temperature control and tactile stimulation are provided at the therapy site.

In Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931 (Fed. Cir. 1990), the Federal Circuit held that a patent that does not set forth a specific computer program for carrying out the claimed invention is valid and properly enabling when "a programmer of reasonable skill could write a satisfactory program with ordinary effort." Northern Telecom, 908 F.2d at 943.

> When the challenged subject matter is a computer program that implements a claimed device or method, enablement is determined from the viewpoint of a skilled programmer using the knowledge and skill with which such a person is charged.

Northern Telecom, 908 F.2d at 941.

With the information provided in the application, one skilled in the art could make and use the novel thermal therapy apparatus recited in the pending claims. One skilled in the programming art is certainly capable of creating, without undue experimentation, a computer program that controls the rate of reservoir/recirculation fluid mixing within the heat exchanger, and turns the pump on and off "for preprogrammed intervals to periodically allow the pressure in the bladder 60 to be cycled between zero and maximum" (page 18, lines 1-3).

As in the Northern Telecom case (908 F.2d at 941):

> The claimed invention... is not in the details of the program writing, but in the apparatus... whose patentability is based on the claimed combination of components... The possible design of superior software, or whether each programmer would work out the details in the identical way, is not relevant in determining whether the inventor has complied with the enablement requirement.

For the above reasons, we submit that the application enables one skilled in the art to make and use the claimed thermal therapy apparatus without undue experimentation. We therefore ask that the rejection based on lack of enablement be withdrawn and an examination based on prior art be conducted.

Please charge any additional fees, or make any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

Date: April 12 1996

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